UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA *ex rel.* DAVID M. KESTER, STATE OF CALIFORNIA *ex rel.* DAVID M. KESTER, STATE OF COLORADO *ex rel.* DAVID M. KESTER, STATE OF CONNECTICUT *ex rel.* DAVID M. KESTER, STATE OF DELAWARE *ex rel.* DAVID M. KESTER, DISTRICT OF COLUMBIA *ex rel.* DAVID M. KESTER, STATE OF FLORIDA *ex rel.* DAVID M. KESTER, STATE OF GEORGIA *ex rel.* DAVID M. KESTER, STATE OF HAWAII *ex rel.* DAVID M. KESTER, STATE OF ILLINOIS *ex rel.* DAVID M. KESTER, STATE OF INDIANA *ex rel.* DAVID M. KESTER, STATE OF LOUISIANA *ex rel.* DAVID M. KESTER, STATE OF MARYLAND *ex rel.* DAVID M. KESTER, STATE OF MASSACHUSETTS *ex rel.* DAVID M. KESTER, STATE OF MICHIGAN *ex rel.* DAVID M. KESTER, STATE OF MINNESOTA *ex rel.* DAVID M. KESTER, STATE OF MONTANA *ex rel.* DAVID M. KESTER, STATE OF NEVADA *ex rel.* DAVID M. KESTER, STATE OF'NEW JERSEY *ex rel.* DAVID M. KESTER, STATE OF NEW MEXICO *ex rel.* DAVID M. KESTER, STATE OF NEW YORK *ex rel.* DAVID M. KESTER, STATE OF NORTH CAROLINA *ex rel.* DAVID M. KESTER, STATE OF OKLAHOMA *ex rel.* DAVID M. KESTER, STATE OF RHODE ISLAND *ex rel.* DAVID M. KESTER, STATE OF TENNESSEE *ex rel.* DAVID M. KESTER, STATE OF TEXAS *ex rel.* DAVID M. KESTER, STATE OF VIRGINIA *ex rel.* DAVID M. KESTER, and STATE OF WISCONSIN *ex rel.* DAVID M. KESTER,

Plaintiffs and Relator,

-against-

No. 11 Civ. 8196 (CM)

NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION,

Defendants.

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MEMORANDUM DECISION AND ORDER DENYING DEFENDANT'S MOTION TO DISMISS

McMahon, J.:

Plaintiff-relator David M. Kester ("Relator") filed a sealed *qui tam* action asserting claims arising under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and related state laws. The Defendants named in the Relator's original complaint included Novartis Pharmaceuticals Corporation ("Novartis") and certain specialty pharmacies, including BioScrip Corporation ("BioScrip"). The United States government ("the Government") subsequently chose to intervene as a plaintiff in this case, but only against Novartis and BioScrip. The Government alleges that Novartis violated the FCA and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), in connection with a kickback scheme.

Pending before the Court is Defendant Novartis's motion to dismiss the Government's Amended Complaint-in-Intervention pursuant to Rule 9(b) of the Federal Rules of Civil Procedure for failure to plead fraud with particularity. For the reasons discussed below, that motion is denied without prejudice.

BACKGROUND[1]

A. Procedural History

Pursuant to the False Claims Act ("FCA"), private persons known as "relators" may file *qui tam* actions and recover damages on behalf of the United States. *See* 31 U.S.C. § 3730(b). Plaintiff Kester ("Relator") originally filed this FCA action in November 2011 on behalf of the United States, 27 states, and the District of Columbia. The original named defendants in the Relator's complaint included Novartis and several pharmacy companies—BioScrip, Accredo

[1] The facts are taken from the Government's Amended Complaint-in-Intervention.

Health Group, Inc., Amerisource Bergen Corporation, Curascript, Inc., CVS Caremark Corporation, Express Scripts, Medco Health Solutions, Inc., Walgreens Company ("Walgreens"), and other pharmacies.[2] The Relator alleged that Novartis and the defendant pharmacies violated the FCA and the Anti-Kickback Statute by engaging in a kickback scheme and then submitting "false claims" for reimbursement to federal and state government programs.

The United States government ("the Government") began investigating the alleged kickback scheme. In April 2013, the Government elected to intervene as a plaintiff in this case, but only against Novartis and BioScrip. In January 2014, Defendant BioScrip settled out of the case. *See* Docket No. 41. Eleven states have since intervened as co-plaintiffs against Novartis.

On January 8, 2014, the Government filed an Amended Complaint-in-Intervention ("the Complaint"). It brings claims against Novartis arising under three subsections of the FCA—31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), and (a)(1)(C). These subsections are discussed in detail below. *See infra* at § I. The Government also asserts state law claims for unjust enrichment and payment by mistake of fact.

Generally, the FCA outlaws the submission of a false or fraudulent "claim" for payment (*i.e.*, a request for reimbursement) to the government. *See id.* at § 3729(a)(1). Such claims may be rendered "false" in a variety of ways. In this case, the Government's FCA claims are predicated on an underlying violation of the Anti-Kickback Statute ("AKS"). Under the AKS, it is illegal to offer a person a kickback in order to "induce" that person to "recommend" the purchase of a drug covered by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). It is likewise illegal to receive a kickback in exchange for "recommending" the purchase of such

[2] The Relator's first complaint is still sealed, so I will not reveal the names of the pharmacies whose involvement in this lawsuit is not public information.

drugs. *See id.* at § 1320a-7b(b)(1). The Government alleges that Novartis conducted two kickback schemes involving drugs covered by Medicare and Medicaid.

B. The Alleged Kickback Schemes

Defendant Novartis is a pharmaceutical company that develops, manufactures, and markets prescription drugs. It sells these drugs through various avenues, one of which is pharmacies. *See* Compl. at ¶ 14.

According to the Government, Novartis realized that certain pharmacies had influence over doctors or patients. So it decided to offer these pharmacies kickbacks to induce them to recommend its drugs to doctors or patients. The first scheme involved an immunosuppressant drug named Myfortic, which is given to patients who receive organ transplants in order to prevent organ rejection. The second kickback scheme involved an iron chelation drug named Exjade, which is given to patients who receive blood transfusions in order to prevent iron overload in the blood.

The pharmacies involved in this case are primarily "specialty pharmacies." Myfortic is distributed by various specialty pharmacies across the United States. Novartis coordinates the dispensing of Exjade through its exclusive distribution network—Exjade Patient Assistance & Support Services ("EPASS"). Through EPASS, Novartis controls which specialty pharmacies receive patient referrals for new Exjade prescriptions. The pharmacies dispense Exjade to patients, contact them about refills, and provide patient "counseling." *Id.* at ¶ 7.

1. Myfortic Scheme

The Government alleges that the Myfortic "switching" kickback scheme lasted from 2005 to 2013. In this scheme, Novartis offered contractual rebates or discounts to "twenty or

more" pharmacies on the condition that they use their influence to recommend that doctors switch (or "convert") transplant patients from other medications to Myfortic. *Id.* at ¶ 4. The pharmacies also agreed to argue against the use of Myfortic's competitors, including a drug named CellCept. The Complaint specifically names five pharmacies engaged in the Myfortic scheme: Baylor Hospital ("Baylor"), Bryant's Pharmacy ("Bryant"), Kilgore's Medical Pharmacy ("Kilgore"), Transcript Pharmacy ("Transcript"), and Twenty-Ten Pharmacy ("Twenty-Ten"). *See id.* at ¶¶ 71-121. The Government also alleges that Novartis had discussions with Walgreens regarding the Myfortic scheme, but it does not assert that Walgreens agreed to the kickback arrangement. *See id.* at ¶¶ 130-40.

The Complaint describes in great detail the mechanics of the Myfortic switching scheme involving Baylor, Bryant, Kilgore, Transcript, and Twenty-Ten. For example, the Complaint states that Novartis targeted Bryant because it recognized that the pharmacy's owner was "very influential" in the Arkansas transplant community due to his relationships with the State Board of Pharmacy, the State Kidney commission, and the largest managed care organization in the state. *Id.* at ¶ 72. Novartis chose to offer Bryant the opportunity to earn significant rebates—up to 15% of its Myfortic sales—in exchange for recommending to both doctors and patients that patients convert from Myfortic's main competitor drug (CellCept) to Myfortic. The more Myfortic that Bryant sold, the higher the rebates it received from Novartis.

Once the scheme began, Novartis closely tracked Bryant's Myfortic and CellCept sales to see how many Bryant patients switched from CellCept to Myfortic. Novartis saw that, "in 3 months," Bryant's owner was able "to convert all [of his transplant] patients from CellCept to Myfortic." *Id.* at ¶ 74. He used his influence with local doctors to "control [Myfortic] market share" and "to increase Myfortic utilization." *Id.* Once a generic (and less costly) form of

CellCept was introduced in 2009, Bryant's owner had discussions with physicians in which he argued against the idea of switching patients from Myfortic to generic CellCept. *See id.* at ¶¶ 77-78.

The Government alleges that Novartis's kickback relationship with Bryant was highly lucrative for both companies. From 2005 to 2009, Novartis saw a tenfold increase in Bryant's annual Myfortic sales, rising from $100,000 to over $1 million. Novartis, in turn, gave Bryant over $650,000 in rebates between 2005 and March 2013 as rewards and as further inducements (*i.e.*, kickbacks) to promote Myfortic. *See id.* at ¶¶ 70, 75.

The Complaint contains similarly detailed allegations regarding Novartis's *quid pro quo* kickback arrangements with Baylor, Kilgore, Transcript, and Twenty-Ten. Each of the pharmacies promised to recommend Myfortic and to attempt to use its influence over doctors or patients to "convert" patients to Myfortic and to prevent patients from switching to CellCept. In exchange, Novartis paid the pharmacies kickbacks in the form of rebates or discounts on all Myfortic sales, whether generated by this influence-peddling campaign or not. *See id.* at ¶¶ 83-121.

2. Exjade Scheme

The Government alleges that the Exjade "refill" kickback scheme lasted from 2007 to 2012. For this scheme, Novartis used its control over patient referrals to induce one pharmacy—BioScrip—to promote Exjade. The Complaint alleges that this scheme began in 2007 when Novartis realized that Exjade's side effects and changing patient population were causing refill orders to decline, leading to a big "performance gap" between Novartis's sales targets and actual Exjade sales. *Id.* at ¶ 173.

Because BioScrip's Exjade sales were lower than those of other pharmacies, Novartis placed the pharmacy under a "performance improvement plan" in February 2007; it imposed new conditions on BioScrip's continued access to its exclusive patient distribution network (EPASS) and its ability to earn rebates, which were $13 per Exjade shipment. *See id.* at ¶ 165. Under this plan, Novartis required BioScrip to commit to increasing the refill rates among its Exjade patients, and to convincing patients who had stopped ordering refills to resume doing so. BioScrip complied with Novartis's demands. Its poorly-trained pharmacy staff called patients to offer purported "counseling" about Exjade therapy. The Government alleges that these calls were actually designed to get patients to order refills, and that Novartis's marketing team was directly involved in formulating BioScrip's "counseling" strategy. *See id.* at ¶¶ 173-84.

By late 2007, Novartis recognized that BioScrip had become very effective in generating refills. Novartis's internal studies stated that "an Exjade patient [at] BioScrip is worth $800-$2,800 more than a patient serviced by another pharmacy." *Id.* ¶ 185. To ensure that BioScrip would continue promoting Exjade refills to patients, Novartis gave the pharmacy benefits including more patient referrals and higher rebates on each sale (*i.e.*, kickbacks). *See id.* ¶¶ 186-92. In exchange, BioScrip committed to "mirror and support Novartis priorities," and it continued to recommend Exjade refills to patients. *Id.* ¶ 193.

The Exjade refill scheme allegedly lasted until 2012, when BioScrip sold its specialty pharmacy division.

C. The Anti-Kickback Statute Compliance Certifications

The Government alleges that, while the two kickback schemes were operating, Novartis and the pharmacies repeatedly "certified" (*i.e.*, represented) that they were complying with the AKS.

The Complaint alleges that the pharmacies had to enter into Medicare provider agreements (CMS Form 855S), which require all participating pharmacies (the "providers" or "suppliers") to certify:

> I agree to abide by the Social Security Act and all applicable Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the *Federal anti-kickback statute* and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

Id. at ¶ 23 (emphasis added). These provider agreements "establish [the pharmacies'] eligibility to participate in the program." *Id.*

The Complaint alleges that state Medicaid enrollment agreements likewise required the pharmacies to certify compliance with "all state and federal laws and Medicaid regulations," including the AKS, "in billing the state Medicaid program for services or supplies furnished." *Id.* at ¶ 36. Additionally, many states required Medicaid providers (like the pharmacies) to "affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations." *Id.* at ¶ 37.

The pharmacies also certified AKS compliance as part of their involvement in the Medicare Part D prescription drug program. For this program, the Department of Health and Human Services ("HHS"), through its component agency the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies ("Part D plan sponsors") to administer prescription drug plans. Part D plan sponsors, in turn, enter into subcontracts with pharmacies to provide drugs to Medicare Part D beneficiaries. The Complaint alleges that, per CMS regulations, these subcontracts must contain language "obligating the pharmacies to comply with

all applicable federal laws, regulations, and CMS instructions," including specifically the AKS. *Id.* at ¶¶ 28-29. The Part D pharmacies must also certify to the "accuracy, completeness, and truthfulness of the [claims] data" they generate. *Id.* at ¶ 32.

Pursuant to CMS regulations, the Part D plan sponsors must certify that they are in compliance with a number of identified federal laws (including specifically the AKS), as well as certify the accuracy of their claims data. *See id.* at ¶¶ 28-31.

As to Novartis, in September 2010 it entered into a settlement agreement with the Government and several states. The settlement arose in response to the filing of civil actions alleging that Novartis committed AKS violations and health care fraud. The settlement agreement states that Novartis had violated the AKS by giving "illegal remuneration . . . to health care professionals to induce them to promote and prescribe" Novartis drugs. *Id.* at ¶ 55.

In conjunction with this settlement, Novartis entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General of HHS ("HHS-OIG"), which requires Novartis to comply with all federal laws, including specifically the AKS. The CIA mandates that executives at Novartis must submit annual certifications to HHS-OIG to attest to their compliance with federal law. It also requires Novartis to notify HHS-OIG in writing "of all probable violations of criminal, civil, or administrative laws applicable to any federal health care program, including violations of the AKS." *Id.* at ¶ 59.

The Government contends that the AKS compliance certifications made by Novartis and the pharmacies during the course of the kickback schemes were false.

D. The Claims for Payment

The Government asserts that, through these two schemes, Novartis knowingly caused the pharmacies[3] to submit thousands of false claims to government programs. The claims were allegedly false, not because the drugs were not provided to patients, but rather because they were "tainted" by the undisclosed kickbacks the pharmacies were receiving from Novartis drug sales. The pharmacies were certifying compliance with the AKS, yet they continued to submit claims for Novartis drugs while receiving kickbacks in violation of that statute.

The Complaint contains detailed data on the claims that BioScrip, Baylor, Bryant, Kilgore, Transcript, and Twenty-Ten submitted to government programs. For example, it alleges the following regarding claims submitted by Transcript:

> Any Medicare or Medicaid claim submitted by Transcript for Myfortic dispensed in connection with its illegal arrangement with Novartis was false and ineligible for reimbursement because such a claim was tainted by kickbacks. In that regard, Medicare data shows that, between August 1, 2011, and February 28, 2013, Transcript submitted 614 Myfortic claims to Medicare Part B and obtained more than $354,000 in reimbursement based on such false claims.

Id. at ¶ 109. The Complaint contains virtually identical allegations for the other five pharmacies. No particular claim that a pharmacy submitted for reimbursement is attached as an exhibit or identified in the pleading; rather, the Government's theory is that all claims for Myfortic and Exjade submitted by Novartis's co-conspirators during the life of the kickback scheme were "false." The falsity lay in the fact that the pharmacies were receiving kickbacks from Novartis for promoting these drugs, in violation of the AKS, yet were certifying, as a condition of Medicare/Medicaid reimbursement, that they were complying with the AKS.

[3] In some cases, financial intermediaries were also involved in submitting the claims. For example, the pharmacy would submit claims to a Medicare Part D plan sponsor, which would then submit the claims to the government. *See* Compl. at ¶¶ 24-27.

The Government alleges that Novartis knew that its kickback schemes would cause the pharmacies to submit false claims to government programs. The Complaint asserts that Novartis was "well aware that Medicare and Medicaid covered a substantial percentage of the Myfortic sales made by the pharmacies to which it was paying kickbacks." *Id.* at ¶ 45. For example, an internal email shows that a Novartis employee reported that 73% of Bryant's patients were covered by Medicare. *See id.* at ¶ 46. The Complaint also alleges that internal Novartis documents show that the company knew that "Medicaid and Medicare constitute ~ 50% of Exjade" sales. *Id.* at ¶ 44.

Because the kickback schemes orchestrated by Novartis allegedly caused the submission of false claims to government programs, the Government asserts several causes of action against Novartis under the False Claims Act.

Novartis moves to dismiss the Government's Complaint pursuant to Rule 9(b) for failure to plead fraud with particularity.

DISCUSSION

I. Fraud Enforcement and Recovery Act

The Government alleges that Novartis committed violations of the FCA from 2005 to 2013. The relevant provisions of the FCA were amended during that time period.

Prior to the FCA amendments contained in the Fraud Enforcement and Recovery Act of 2009 ("FERA"), the three relevant subsections were numbered 31 U.S.C. §§ 3729(a)(1), (a)(2), and (a)(3). They established civil liability where a defendant: (a) "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval," *id.* § 3729(a)(1), (b) "knowingly makes, uses, or causes to be made or used, a false record or

statement to get a false or fraudulent claim paid or approved by the Government," *id.* § 3729(a)(2), or (c) "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid," *id.* § 3729(a)(3).

Congress enacted FERA to, among other things, "clarif[y] that liability under section 3729(a) attaches whenever a person knowingly makes a false claim to obtain money or property, any part of which is provided by the Government without regard to whether the wrongdoer deals directly with the Federal Government; with an agent acting on the Government's behalf, or with a third party contractor, grantee, or other recipient of such money or property." *U.S. ex rel. Osmose, Inc. v. Chemical Specialties, Inc.*, No. 09 Civ. 425, 2014 WL 234819, at *5 (W.D.N.Y. Jan. 22, 2014) (quoting S. Rep. No. 111-10, 2009 WL 787872, *11 (2009)).

As amended by FERA, the three subsections now create civil liability where a defendant: (a) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," *id.* § 3729(a)(1)(A); (b) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B); or (c) "conspires to commit a violation of" another subsection of the FCA, *id.* § 3729(a)(1)(C).

The current version of the FCA also defines a "claim" as "any request or demand . . . for money or property" that: "(i) is presented to an officer, employee, or agent of the United States," or "(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government . . . provides or has provided any portion of the money or property requested or demanded." *Id.* at § 3729(b)(2)(A).

The Government asserts two counts under each of the three FCA subsections—one for the Myfortic scheme, and one for the Exjade scheme. Counts 1 and 5 assert causes of action

under pre-FERA subsection (a)(1) and post-FERA subsection (a)(1)(A), Counts 2 and 6 assert causes of action under pre-FERA subsection (a)(2) and post-FERA subsection (a)(1)(B), and Counts 3 and 7 assert causes of action under pre-FERA subsection (a)(3) and post-FERA subsection (a)(1)(C).

FERA provides that the amendment to former subsection (a)(2)—now subsection (a)(1)(B)—"shall take effect as if enacted on June 7, 2008." Pub. L. No. 111–21, § 386, 123 Stat. 1617 (2009). The Second Circuit has applied this amendment to all legal claims pending before a court on or after June 7, 2008. *See U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 113 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011). As Counts 2 and 6 are legal claims pending after that date, the new subsection (a)(1)(B) governs Counts 2 and 6 for the entire duration of the alleged scheme.

The FERA amendments to subsections (a)(1) and (a)(3), however, were prospective only. *See U.S. ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 811 n.36 (S.D.N.Y. 2010). So in this action, the pre-amendment subsections apply to acts committed prior to FERA's effective date—May 20, 2009—and the post-amendment subsections apply to acts committed after that date.

The Court notes this statutory history only for clarity; the amendments do not affect the outcome of the present motion, which raises only the sufficiency of the pleading's allegations of fraud under Rule 9(b). When it becomes necessary to refer to the statute, I will use the amended FCA subsection designations throughout this opinion.

II. Rule 9(b) and the False Claims Act

Where a cause of action sounds in fraud, the plaintiff must satisfy the heightened pleading standard of Rule 9(b). *See Rombach v. Chang*, 355 F.3d 164, 170-71 (2d Cir. 2004).

Because the FCA is an "anti-fraud statute," claims brought under that statute "fall within the express scope of Rule 9(b)." *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995); *see also Wood ex rel. U.S. v. Applied Research Assocs., Inc.*, 328 Fed. App'x 744, 747 (2d Cir. 2009). This rule provides that a party alleging fraud "must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). Scienter, however, "may be alleged generally." *Id.*

To comply with Rule 9(b), a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Rombach*, 355 F.3d at 170. "In other words, Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04 Civ. 704, 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (quoting *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997)).

The particularity requirement of Rule 9(b) serves several purposes: "to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *Rombach*, 355 F.3d at 171. It also "discourage[s] the filing of complaints as a pretext for discovery of unknown wrongs." *Madonna v. U.S.*, 878 F.2d 62, 66 (2d Cir. 1989) (citation omitted).

A plaintiff must plead all the "circumstances constituting fraud or mistake" with sufficient particularity to fulfill the purposes of Rule 9(b). FED. R. CIV. P. 9(b). For the various subsections of the FCA, these "circumstances" depend upon the elements of the subsection at

issue. However, Novartis alleges that *all* counts are insufficiently pleaded for one reason: the Government fails to identify with particularity the precise false claims that were submitted.

A. For Claims Under Subsections (a)(1)(A) and (a)(1)(B), Plaintiffs Must Plead the Submission of False Claims with a High Degree of Particularity.

Subsection (a)(1)(A) provides for liability where the defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." *Id.* § 3729(a)(1)(A). To prove a claim under this subsection, a plaintiff must show that: (1) there was a false or fraudulent claim, (2) the defendant knew it was false or fraudulent, (3) the defendant presented the claim, or caused it to be presented, to the United States, and (4) it did so to seek payment from the federal treasury. *See Mikes*, 274 F.3d at 695; *U.S. ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 811 (S.D.N.Y. 2010).

Subsection (a)(1)(B) provides for liability where the defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). To prove a claim under this subsection, a plaintiff must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim. *See Pervez*, 736 F. Supp. 2d at 811. Thus, this subsection contains a "double falsity" requirement—the plaintiff must plead both a false statement and a corresponding false claim. *U.S. ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 655 (S.D.N.Y. 2011).

The Government has pleaded in great detail two fraudulent schemes that allegedly caused claims submitted by the pharmacies to be "false or fraudulent" within the meaning of the FCA. But subsection (a)(1)(A) also requires a plaintiff to plead with particularity that false claims were actually submitted to the government. *See Polansky*, 2009 WL 1456582, at *5. And while few

cases explicitly distinguish between subsection (a)(1)(A) and (a)(1)(B) on this issue, I agree with my colleague Judge Mordue in the Northern District of New York that plaintiffs asserting subsection (a)(1)(B) claims must likewise plead the "claim" submission element with particularity. *See U.S. ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 09 Civ. 710 (NAM/DEP), 2011 WL 167246, at *10-12 (N.D.N.Y. Jan. 19, 2011); *see also U.S. ex rel. Siegel v. Roche Diagnostics Corp.*, No. 11 Civ. 5378 (ADS)(AKT), 2013 WL 6847689, at *4 (E.D.N.Y. Dec. 30, 2013).

In short, the submission of a "claim" is an essential element of causes of action under subsections (a)(1)(A) and (a)(1)(B). *See U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *U.S. ex rel. Moore v. GlaxoSmithKline, LLC*, No. 06 Civ. 6047, 2013 WL 6085125, at *3 (E.D.N.Y. Oct. 18, 2013); *Blundell*, 2011 WL 167246, at *10-12. The FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'" *Polansky*, 2009 WL 1456582, at *5 (quoting *U.S. v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)). Thus, the submission of a false claim is the "*sine qua non* of a False Claims Act violation." *Clausen*, 290 F.3d at 1311.

Accordingly, a plaintiff "cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted." *Polansky*, 2009 WL 1456582, at *5. He must also plead the "claim" submission element with particularity.

Courts generally agree that Rule 9(b) requires a plaintiff asserting a subsection (a)(1)(A) claim to plead the submission of a false claim with particularity. However, they differ over what constitutes "particularity." Because there is no published Second Circuit decision addressing this issue, I will survey the cases from other Circuit courts.

Some Circuits require a plaintiff to plead a fraudulent scheme in detail but allow him to provide only minimal factual basis for the allegation that claims that were actually submitted as a result of the scheme. *See U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010); *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009). In other words, these courts permit plaintiffs to plead the "claim" element with a relatively low degree of particularity.

In *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), the Fifth Circuit squarely addressed the question of how to apply Rule 9(b) to the "claim" element in FCA cases—"with what particularity a complaint must plead the actual details of the false claim itself." *Id.* at 188. The court acknowledged that the Fifth Circuit had "traditionally required that a fraud complaint include 'the time, place and contents of the false representation[], as well as the identity of the person making the misrepresentation and what that person obtained thereby.'" *Id.* (quoting *U.S. ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 308 (5th Cir. 1999)). However, the court emphasized, the requirements of Rule 9(b) are ultimately "context-specific." *Id.*

The *Grubbs* court distinguished the FCA context from the common law fraud context in which the "time, place, contents, and identity" standard originated. *Id.* It pointed out that common law fraud requires a plaintiff to prove the elements of reliance and damages, which "heighten the need for attention to the misrepresentation itself." *Id.* at 189. The court reasoned that, because FCA claims do not require a plaintiff to prove either reliance or damages, "the contents of the bill are less significant." *Id.* It therefore concluded that "a claim under the False Claims Act and a claim under common law or securities fraud are not on the same plane in

meeting the requirement of 'stat[ing] with particularity' the contents of the fraudulent misrepresentation." *Id.*

Because of these differences, the *Grubbs* court established a more lenient standard for satisfying Rule 9(b) in the FCA context. It held that "a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with *reliable indicia* that lead to a strong inference that claims were actually submitted." *Id.* at 190 (emphasis added). Thus, the *Grubbs* court required a high degree of particularity regarding the fraudulent scheme ("particular details") but a lesser degree of particularity regarding the submission of a false claim ("reliable indicia"). The court gave an example of "reliable indicia" that claims were submitted—"dates that services were fraudulently provided or recorded, by whom, and evidence of the department's standard billing procedure." *Id.* at 189. The court also stated that "a plaintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted." *Id.* at 190.

The *Grubbs* court then applied this "reliable indicia" standard to the complaint before it. The defendants in the case included several psychiatrists and the hospital that employed them; the plaintiff was a doctor who had recently joined the practice. The complaint gave a detailed description of the psychiatrists' discussions with the plaintiff in which they urged him to participate in their scheme to submit false bills to Medicare and Medicaid for "face-to-face visits" with patients that never actually occurred. *See id.* at 184. It further stated that the nursing staff at the hospital tried to help the plaintiff record patient visits that never occurred. The complaint provided specific dates on which the psychiatrists falsely claimed to have visited patients, as well as information regarding the hospital's standard billing practices. For each

defendant psychiatrist, the complaint averred at least one instance of false billing similar to the following: "Dr. Desai billed Medicaid for psychotherapy services on January 8, 2004, CPT Code #90805, which constituted a false claim in that the medical records indicate that no psychotherapy was provided by Desai on that date." *Id.* at 185.

The Fifth Circuit held that the complaint satisfied Rule 9(b). *See id.* at 191. It stated that the allegations "amount[ed] to more than probable, nigh likely, circumstantial evidence that the doctors' fraudulent records caused the hospital's billing system *in due course* to present fraudulent claims to the Government." *Id.* at 192 (emphasis added).

The "reliable indicia" standard described by the Fifth Circuit in *Grubbs*—that a plaintiff can simply "alleg[e] particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted"—represents an admittedly lenient interpretation of Rule 9(b). *Id.* at 190. The court explicitly stated that it would have been sufficient for the plaintiff to provide "reliable indicia" in the form of "dates that services were fraudulently provided or recorded, by whom, and evidence of the department's standard billing procedure," *id.* at 189; thereafter, the plaintiff could apparently rely on an inference that the hospital followed its standard procedure and submitted a claim to a government program "in due course." *Id.* at 192.[4]

The Government argues that the Court should apply the lenient *Grubbs* standard here. But in the view of this Court, the *Grubbs* standard borders on requiring no particularity for the "claim" element at all. It allows the plaintiff to make fairly conclusory allegations that claims were submitted for medical services pursuant to a standard billing practice. As the Eleventh

[4] It is worth noting, however, that the complaint at issue in *Grubbs* actually provided far more detail about the submission of specific false claims. For each defendant psychiatrist, it identified a particular date on which a particular doctor billed for a particular service to a particular government program using a particular code. Thus, given the billing details provided by the plaintiff in *Grubbs*, the complaint could have even survived Rule 9(b) scrutiny under a stricter standard.

Circuit stated in *United States ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002):

> We cannot make assumptions about a False Claims Act defendant's submission of actual claims to the Government without stripping all meaning from Rule 9(b)'s requirement of specificity or ignoring that the "true essence of the fraud" of a False Claims Act action involves an actual claim for payment and not just a preparatory scheme.

Id. at 1312 n.21. The *Clausen* court went on to say that Rule 9(b) does not permit a plaintiff asserting an FCA claim to "describe a private scheme in detail" and then simply allege that "claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *Id.* at 1311. Rather, the plaintiff must allege with particularity "*an actual false claim* for payment being made to the Government." *Id.* (emphasis added).

I agree. A complaint's description of a fraudulent scheme paired with information about a defendant's standard billing practice is not enough "particular" information to fulfill the purposes of Rule 9(b); the plaintiff must provide a detailed factual basis to support his allegation that the defendant submitted a false claim *in this specific instance*, not just that the defendant had a custom of submitting claims. *See U.S. ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 87 (D. Conn. 2006). To the extent the *Grubbs* "reliable indicia" standard suggests that a plaintiff may rely on bald assertions that a false claim would have been submitted pursuant to a standard billing procedure, this Court rejects that standard as incompatible with Rule 9(b).

The better rule was set forth by the First Circuit in *United States ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220 (1st Cir. 2004): a plaintiff must plead both the particular details of a fraudulent scheme and "details that *identify particular false claims for payment* that were submitted to the government." *Id.* at 232 (emphasis added). Under this rule,

both the fraudulent scheme and the submission of false claims must be pled with a high degree of particularity.

The *Karvelas* court described the types of details about the claims that can satisfy Rule 9(b) under its "identification" standard as follows:

> [D]etails concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a [plaintiff] to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However, . . . we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

360 F.3d at 232-33. The *Karvelas* rule is that, although there is no mandatory "checklist" of identifying information that a plaintiff must provide, the complaint must include sufficient details about the false claims such that the defendant can reasonably "identify [the] particular false claims for payment" that are at issue. *Id.* at 232.

Other Circuit courts apply comparably strict particularity standards. *See also U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457-58 (4th Cir. 2013); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 470 (6th Cir. 2011); *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 509 (6th Cir. 2007); *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727-28 (10th Cir. 2006); *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1313 (11th Cir. 2002).

Given that submission of a false claim is an essential element of subsections (a)(1)(A) and (a)(1)(B), requiring a plaintiff to provide enough detail for a defendant to be able to reasonably identify particular claims that are allegedly false better fulfills the central purpose of

Rule 9(b)—providing fair notice to the defendant. *See Rombach*, 355 F.3d at 171; *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318, 338 (D. Conn. 2004). It also weeds out FCA claims brought by plaintiffs who are merely speculating that false claims might have been submitted to the government. This serves the other purposes of Rule 9(b): safeguarding defendants' reputations from improvident charges of wrongdoing, protecting defendants from strike suits, and discouraging the filing of suits as a pretext for the discovery of unknown wrongs. *See Rombach*, 355 F.3d at 171; *Madonna*, 878 F.2d at 66. As the court stated in *Clausen*: "[W]e cannot be left wondering whether a plaintiff has offered mere conjecture or a specifically pleaded allegation on an essential element of the lawsuit." 290 F.3d at 1313.

Though no Second Circuit opinion addresses the degree of particularity with which a plaintiff asserting an FCA claim must plead the submission of a false claim, the court has issued a summary order on the subject. In *Wood ex rel. United States v. Applied Research Associates, Inc.*, 328 Fed. App'x 744 (2d Cir. 2009), the court affirmed the district court's dismissal of an FCA action on the basis that the plaintiff failed to satisfy Rule 9(b). The complaint in *Wood* described the alleged fraudulent scheme and then stated, in conclusory fashion: "As a result of defendants' false statements and false or fraudulent reports and other submissions . . . defendants wrongfully obtained payments from [a government agency] which they knew or should have known they were not entitled to receive, by virtue of the fraud . . ." *Id.* at 749. The court stated that these allegations were "plainly insufficient under Rule 9(b)." *Id.* It quoted approvingly from the district court opinion, which stated that "the Amended Complaint 'do[es] not cite to a single *identifiable record or billing submission* they claim to be false, or give a single example of when a purportedly false claim was presented for payment by a particular defendant at a specific

time.'" *Id.* at 750 (citation omitted) (emphasis added). Accordingly, the court dismissed the subsection (a)(1)(A) and (a)(1)(B) claims under Rule 9(b).

Wood lacks precedential value, but it strongly suggests that the Second Circuit would approve a pleading rule comparable to the "identification" standard articulated in *Karvelas*, and would require plaintiffs asserting subsection (a)(1)(A) and (a)(1)(B) claims to plead the submission of a false claim with a high degree of particularity in order to satisfy Rule 9(b).

In the judgment of this Court, it seems highly unlikely that the Second Circuit would adopt the *Grubbs* rule. Unlike the *Grubbs* court, the Second Circuit has never suggested that Rule 9(b) should be applied with any less rigor in the FCA context as compared to the common law or securities fraud context. On the contrary, the *Wood* court cited a securities fraud case when describing the particularity requirement for FCA cases as follows: "To satisfy the pleading requirements of Rule 9(b), a complaint must '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" 328 Fed. App'x at 747 (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994)). The court likewise cited cases from the common law and securities fraud contexts when describing the purposes of Rule 9(b). *See id.*

In sum, *Wood* gave no indication that the Second Circuit (like the Fifth Circuit) views an FCA claim as "not on the same plane" as other fraud claims with respect to the particularity required by Rule 9(b). *Grubbs*, 565 F.3d at 189. Quite the opposite—*Wood* implies that the Second Circuit requires a high degree of particularity in the FCA context as well.

Further, the weight of authority from district courts within this Circuit is that plaintiffs asserting subsection (a)(1)(A) and (a)(1)(B) claims must plead the submission of a false claim

with a high degree of particularity. *See U.S. ex rel. Osmose, Inc. v. Chemical Specialties, Inc.*, No. 09 Civ. 425, 2014 WL 234819, at *9 (W.D.N.Y. Jan. 22, 2014); *Siegel*, 2013 WL 6847689, at *4; *Moore*, 2013 WL 6085125, at *3; *Mooney*, 2013 WL 1346022, at *3; *U.S. ex rel. Chen v. EMSL Analytical, Inc.*, No. 10 Civ. 504, 2013 WL 4441509, at *16 (S.D.N.Y. Aug. 16, 2013); *Blundell*, 2011 WL 167246, at *10; *U.S. ex rel. Smith v. New York Presbyterian Hosp.*, No. 06 Civ. 4056 (NRB), 2007 WL 2142312, at *7 (S.D.N.Y. July 18, 2010); *Johnson v. The Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 265 (W.D.N.Y. 2010); *Polansky*, 2009 WL 1456582, at *5; *U.S. ex rel. Reynolds v. Sci. Applications Int'l Corp.*, No. 07 Civ. 4612 (GBD), 2008 WL 2566747, at *5 (S.D.N.Y. June 26, 2008); *U.S. ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 85 (D. Conn. 2006).

A number of these district courts have explicitly adopted the *Karvelas* "identification" standard in requiring a high degree of particularity. *See Moore*, 2013 WL 6085125, at *3; *Mooney*, 2013 WL 1346022, at *3; *Chen*, 2013 WL 4441509, at *16; *Polansky*, 2009 WL 1456582, at *5; *Smith*, 415 F. Supp. 2d at 85.

To this Court's knowledge, only one district court in the Second Circuit has applied the *Grubbs* "reliable indicia" standard—the more lenient standard—to determine whether a plaintiff has pled the submission of a false claim with the requisite particularity. *See U.S. v. Huron Consulting Grp., Inc.*, 09 Civ. 1800 (JSR), 2011 WL 253259, at *2 (S.D.N.Y. Jan. 24, 2011). Several other courts in this Circuit have explicitly rejected *Grubbs* in favor of the more exacting standard. *See Osmose*, 2014 WL 234819, at *9; *Siegel*, 2013 WL 6847689, at *4; *Moore*, 2013 WL 6085125, at *5.

In line with the weight of authority in this Circuit, I adopt the *Karvelas* standard—plaintiffs asserting subsection (a)(1)(A) and (a)(1)(B) claims must plead the submission of a false

claim with a high enough degree of particularity that defendants can reasonably "identify particular false claims for payment that were submitted to the government." 360 F.3d at 232. This stricter standard serves the purposes of Rule 9(b) by requiring plaintiffs to both (1) identify which of the claims submitted were "false" and (2) provide factual support (as opposed to mere speculation) for their assertions that claims were actually submitted to a government program. This means that the Government must provide particulars of allegedly false claims in connection with Counts 1, 2, 5, and 6 of its Complaint.

B. Plaintiffs Must Reasonably Identify the False Claims at Issue, But They Need Not Specify Every Single False Claim.

But *Karvelas* does not mean that an FCA complaint will be dismissed unless the plaintiff identifies by claim number each and every individual claim that it contends was false.

In cases where the alleged fraudulent scheme is extensive and involves "numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct." *Cardiac Devices*, 221 F.R.D. at 333. Pleading the specifics of thousands of claims would be "cumbersome, unwieldy, and would accomplish no purpose." *Id.* at 338.

Instead, the complaint must provide the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue. In cases with extensive schemes, plaintiffs can satisfy this requirement in two ways: (1) providing sufficient identifying information about all the false claims, or (2) providing example false claims.

The *Karvelas* court gave examples of the kind of identifying information that a plaintiff can provide in order to satisfy Rule 9(b): dates of claims, contents of claims, identification numbers, reimbursement amounts, goods or services provided, and individuals involved in the

billing. *See* 360 F.3d at 232-33. In the health care fraud context, courts also note the usefulness of data such as the name of the patient who received the good or service, the name of the medical professional who provided the good or service, the date on which the good or service was delivered, the name of the employee who submitted the claim, and the government entity that reimbursed the claim. *See Bledsoe*, 501 F.3d at 515; *Mooney*, 2013 WL 1346022, at *4; *Polansky*, 2009 WL 1456582, at *3; *Smith*, 415 F. Supp. 2d at 86; *Cardiac Devices*, 221 F.R.D. at 336; *Blundell*, 2011 WL 167246, at *11.

As the *Karvelas* court noted, this is not a "checklist of mandatory requirements" for every FCA complaint. 360 F.3d at 233. "Rule 9(b) does not impose a 'one size fits all' list of facts that must be included in every FCA complaint." *Cardiac Devices*, 221 F.R.D. at 337-38. Ultimately, whether a complaint satisfies Rule 9(b) "depends upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading." *Wells Fargo*, 2013 WL 5312564, at *16. It is a fact-specific inquiry.

In *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318 (D. Conn. 2004), the government alleged that the defendant hospitals had defrauded Medicare by submitting bills for medical procedures involving cardiac devices that had not been approved by the Food and Drug Administration ("FDA"). Because the FDA had not approved the devices, the procedures were not eligible for reimbursement under federal law; thus, the government argued, the claims for repayment were "false" under the FCA. The government alleged that the defendants submitted a total of 9,848 false claims pursuant to the scheme. In the complaints against the various hospitals, the government provided detailed "categorical information" about the thousands of

false claims submitted. *Id.* at 336. For each hospital, the complaint alleged that the defendant received "millions of dollars in Medicare and Medicaid reimbursements" between 1986 and 1995, and it broke down the number of procedures performed for each particular unapproved cardiac device. *Id.* at 329-30. The government separately served each hospital with a patient list that provided further specifics on each procedure: "the patient's name, account number and medical records number, the admission and discharge dates, and information on the device that was used." *Id.* at 330 n.23. These lists were not attached to the complaints.

The *Cardiac Devices* court held that the complaints, "when read in conjunction with" the patient lists served on the hospitals, "sufficiently identified the submission of specific false claims." *Id.* at 337. The court concluded that the hospitals had enough information to be able to figure out which claims for cardiac procedures were at issue; it did not require comprehensive details about each of the 9,848 claims. Accordingly, a plaintiff satisfies Rule 9(b) where he provides a reasonable amount of identifying information about the numerous false claims submitted.

Alternatively, plaintiffs can plead the submission of thousands of claims with particularity by providing example claims which are representative of those arising from the fraudulent scheme. *See Mooney*, 2013 WL 1346022, at *7; *Wells Fargo*, 2013 WL 5312564, at *17; *U.S. ex rel. Tiesinga v. Dianon Sys., Inc.*, 231 F.R.D. 122, 124 (D. Conn. 2005).

In *United States v. Wells Fargo Bank, N.A.*, No. 12 Civ. 7527 (JMF), 2013 WL 5312564 (S.D.N.Y. Sept. 24. 2013), the government alleged in its complaint that between 2001 and 2005 the defendant bank certified that "tens of thousands" of home mortgage loans were eligible for Federal Housing Administration ("FHA") insurance, when in reality some of the loans were not high enough in quality to meet the eligibility criteria. *Id.* at *4. The complaint estimated that

32.9% of the loans violated regulations and were, therefore, ineligible for FHA insurance. Once the homeowners defaulted on the low-quality loans, the bank allegedly submitted thousands of "false" insurance claims which corresponded with the ineligible loans.

The *Wells Fargo* court stated that "it would be impractical, if not impossible, to require that the Government plead the details of each and every false claim." *Id.* at *16. Instead, the government submitted "ten examples of insurance claims, identified by FHA case number, paid by [the Department of Housing and Urban Development] on loans the Government alleges Wells Fargo falsely certified as eligible for FHA insurance as a result of this scheme." *Id.* at *17. The court deemed these examples to be sufficiently representative of the claims flowing from the entire scheme described in the complaint, because they were taken from throughout the time period of the scheme, and they were representative with respect to substantive content. Thus, the court held that the government's complaint satisfied Rule 9(b) with respect to the entire scheme. *See id.*

In *Wells Fargo*, the example claims were especially useful because the theory of fraud required loan-by-loan analysis to determine which insurance claims were rendered "false" by the bank's certifications. Some of the thousands of loans implicated in the complaint met the eligibility criteria for FHA insurance, while others did not; thus, the bank's eligibility certifications were only false with respect to a subset of the insurance claims. The fact that the complaint described the fraudulent scheme and specified the time span of the scheme was not enough to give the defendant fair notice; the bank needed more information to be able to reasonably identify which of the FHA insurance claims submitted during that time span were false. The example claims filled that gap in the complaint's particularity, because the bank could use the examples to deduce which of the other claims were alleged to be "false."

In sum, a plaintiff asserting a claim under subsection (a)(1)(A) or (a)(1)(B) must plead the submission of false claims with a high enough degree of particularity that defendants can reasonably "identify particular false claims for payment that were submitted to the government." *Karvelas*, 360 F.3d at 232. The details included in the complaint must fulfill the purposes of Rule 9(b) by both (1) identifying which of the claims the defendant submitted were "false," and (2) providing a factual basis to support the plaintiff's assertion that claims were actually submitted to a government program. Where numerous false claims are involved, the plaintiff may satisfy Rule 9(b) by providing sufficient identifying information about those false claims, or by providing example false claims that enable the defendant to identify similar claims; the Second Circuit has not demonstrated a preference for either method of pleading the submission of numerous false claims.

C. The Government's Theory of Claim "Falsity"

Because the question of whether a complaint satisfies Rule 9(b) ultimately "depends upon the nature of the case," *Wells Fargo*, 2013 WL 5312564, at *16, this Court cannot apply the *Karvelas* standard to the Government's Complaint without examining the Government's theory of claim "falsity" under the FCA.

1. "False" Claims Generally

As noted above, the FCA broadly defines a "claim" as "any request or demand . . . for money or property" that: "(i) is presented to an officer, employee, or agent of the United States," or "(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government . . . provides or has provided any portion of the money or property

requested or demanded." *Id.* at § 3729(b)(2)(A). Requests for reimbursement of health care expenses that are submitted to Medicare and Medicaid qualify as "claims" under the FCA. *See New York v. Amgen Inc.*, 652 F.3d 103, 111 (1st Cir. 2011); *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001).

In *Mikes v. Straus*, the Second Circuit defined a false or fraudulent claim as one "aimed at extracting money the government otherwise would not have paid." *Id.* at 696. There are two types of "falsity"—*i.e.*, two reasons that the government would not pay the claim if it knew the true facts. One is factual falsity; the other is legal falsity. *See id.* at 697.

A claim is "factually false" where the party submitting the claim supplies "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.*; *see also Pervez*, 736 F. Supp. 2d at 812. In other words, the party "bills for something it did not provide." *Kirk*, 601 F.3d at 113.

In contrast, a "legally false" claim does not misrepresent the goods and services provided. Rather, the party submitting the claim falsely represents (or "certifies") compliance with a statute, regulation, or contractual provision, where compliance is a precondition to government payment of the claim. *See Mikes*, 274 F.3d at 697. The Second Circuit's requiring that compliance with a particular statute is a "precondition" to payment restricts the types of statutory violations that can lead to FCA liability. The "preconditions" to payment of claims vary by government program and by type of claim, and they are the product of changing statutes, regulations, and individual contracts. For example, Medicare may have different preconditions depending on what good or service is at issue. State Medicaid programs likewise vary in their requirements.

Mikes established the analytical framework for the "false certification" theory of legal "falsity" in the Second Circuit. *See id.* at 697-99. There are two types of false certifications: express and implied.

As the name suggests, an "express false certification" occurs when the party submitting the claim expressly and "falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Mikes*, 274 F.3d at 698. This only occurs when the government actually requires a party to expressly certify that it is in compliance with a statute, and the party does so while not actually complying with that statute.

But FCA liability can also arise on a theory of "implied false certification." The implied false certification theory is "based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id.* at 699. The Second Circuit has stated that this theory "is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Id.* at 700 (emphasis in original). "Liability under the Act may properly be found . . . when a defendant submits a claim for reimbursement while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant." *Id.*

Most Circuit courts have adopted the "false certification" theory of legal "falsity" described in *Mikes*. *See U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 306 (3d Cir. 2011); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467 (6th Cir. 2011); *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1167-71 (10th Cir. 2010); *U.S. ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005); *U.S. ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000); *Harrison v. Westinghouse Savannah*

River Co., 176 F.3d 776, 786-87 (4th Cir. 1999); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996). The First Circuit has implemented a less rigid version of legal "falsity" that does not rely as heavily on the distinctions between "express" and "implied" certifications. *See New York v. Amgen Inc.*, 652 F.3d 103, 110 (1st Cir. 2011).

District courts in this Circuit routinely recognize the "express" and "implied" false certification theories of claim falsity. *See Wells Fargo*, 2013 WL 5312564, at *21; *Feldman*, 808 F. Supp. 2d at 651-52; *Blundell*, 2011 WL 167246, at *15; *Polansky*, 2009 WL 1456582, at *7; *Cardiac Devices*, 221 F.R.D. at 335-36.

Here, the Government argues that the claims submitted in connection with the kickback scheme were both factually and legally "false." *See* Docket No. 163 at 6. This Court can easily dispose of the "factual" falsity argument, because nowhere in the Complaint does the Government allege that any pharmacy "bill[ed] for something it did not provide," *Kirk*, 601 F.3d at 113, by submitting claims with "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Mikes*, 274 F.3d at 697. The Government does not assert that any of the claims submitted by the pharmacies misrepresented that Myfortic or Exjade was actually dispensed to a patient.

Rather, the Government's theory is more accurately characterized as "legal" falsity—it contends that the pharmacies' claims for reimbursement of Myfortic and Exjade claims were false because they were tainted by violations of the Anti-Kickback Statute. The Government asserts that Novartis and the pharmacies certified compliance with the AKS when, in fact, Novartis was paying kickbacks to the pharmacies in exchange for their promises to promote Myfortic or Exjade.

The Government has alleged that the claims submitted by the pharmacies were legally false under both the express false certification theory and the implied false certification theory.

2. Legal "Falsity" and the Anti-Kickback Statute

The Government's theories of "express" and "implied" false certifications are predicated on underlying AKS violations.

The AKS makes it illegal to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person" to "purchase or . . . recommend purchasing" a drug that is covered by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). Likewise, the AKS outlaws "knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate)" "in return for purchasing . . . or recommending purchasing" a drug covered by a federal health care program. *Id.* at § 1320a-7b(b)(1). Thus, the AKS forbids offering, paying, soliciting, or receiving kickbacks in exchange for recommending drugs covered by Medicare and Medicaid.

An HHS-OIG "Special Fraud Alert" issued in 1994 provided the public with examples of pharmaceutical "marketing programs" that violate the AKS. *See* 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994). According to this publication, the AKS prohibits "product conversion" programs in which "Drug Company A offer[s] a cash award to pharmacies for each time a drug prescription [is] changed from Drug Company B's product to Drug Company A's product." *Id.* Likewise, the alert notified the public that it is illegal for a pharmaceutical company to offer pharmacies remuneration (and for pharmacies to accept it) in exchange for performing "marketing tasks," such as "sales-oriented 'educational' or 'counseling' contacts, or physician and/or patient outreach," when these acts occur "in the course of pharmacy practice related to Medicare or Medicaid." *Id.* The alert went on to state: "If one purpose of any of these

marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid,[5] then the criminal anti-kickback statute is implicated." *Id.* Novartis does not dispute that such activities constitute AKS violations.

Notably, the AKS does not require a kickback scheme to succeed in generating new business (*i.e.*, new patient prescriptions) in order for a violation to have occurred. *See U.S. ex rel. Parikh v. Citizens Med. Ctr.*, No. 10 Civ. 64, 2013 WL 5304057, at *6 (S.D. Tex. Sept. 20, 2013). A pharmaceutical company violates the AKS if it "offers" a pharmacy a kickback "to induce" the pharmacy to "recommend[] purchasing" the company's drugs. 42 U.S.C. § 1320a-7b(b)(2). And the pharmacy violates the AKS if it "receives" a kickback "in return for . . . recommending purchasing" those drugs. *Id.* at § 1320a-7b(b)(1). The pharmacy violates the AKS even if it only "solicits" a kickback in exchange for recommending drugs covered by government programs. *Id.* Thus, it is the kickback arrangement itself that constitutes the AKS violation, not the success of the arrangement. The illegal recommendations in question do not have to actually convince someone to purchase the drugs who would not have otherwise done so.

As discussed above, the Government contends that Novartis and the pharmacies violated the AKS through two kickback schemes. It alleges that the schemes involved particular pharmacies (BioScrip, Baylor, Bryant, Kilgore, Transcript, and Twenty-Ten), particular drugs (Myfortic and Exjade), and particular time periods (between 2005 and 2013). The Government asserts that the essence of the schemes was the "recommending" of drugs—Novartis offered the pharmacies remuneration (and the pharmacies accepted it) in exchange for their efforts (1) to persuade physicians to switch more patients to Myfortic or (2) to promote Exjade to patients by encouraging them to purchase more refills. According to the Government, the success of a

[5] Though the HHS-OIG Special Fraud Alert only mentions Medicaid in this particular passage, the same rule applies to prescription drugs reimbursable by Medicare, given that the AKS applies to drugs covered by either program. *See* 42 U.S.C. § 1320a-7b(b).

pharmacy's recommendation in generating sales was not a prerequisite for Novartis's payment of kickbacks on each sale; the pharmacies received kickbacks for every sale of Myfortic or Exjade, regardless of whether the sale was brought about by the pharmacy's efforts. For example, Bryant collected a percentage rebate (up to 15%) on every sale of Myfortic, and BioScrip received a $13 rebate on every sale of Exjade. At this stage of the proceeding, I assume these allegations to be true.

Thus, the Government argues, Novartis and the pharmacies were violating the AKS in connection with Myfortic and Exjade drug sales during the course of the kickback scheme. To prove its FCA claims, the Government must then demonstrate that these underlying AKS violations led to the submission of false claims.

The Government contends that compliance with the AKS is a "precondition" to Medicare or Medicaid reimbursement; thus, no claim is eligible for payment when the pharmacy submitting the claim is violating the AKS in connection with that claim. The Second Circuit has not decided whether compliance with the AKS is a precondition to the payment of claims submitted to Medicare or Medicaid. District courts in this Circuit have simply assumed that underlying AKS violations can lead to "false claims" under the FCA. *See Moore*, 2013 WL 6085125, at *1; *Mooney*, 2013 WL 1346022, at *4; *Blundell*, 2011 WL 167246, at *15.

The Government also alleges that the pharmacies[6] made "express" and "implied" false certifications to Medicare and Medicaid, representing that they were in compliance with the AKS. First, as participants in these federal programs, the pharmacies were required to periodically submit paperwork (including the provider agreements and Medicare Part D

[6] It is worth noting that the Government could have argued that the AKS compliance certifications made by Novartis and the Medicare Part D plan sponsors were "false," and that they rendered the claims for Myfortic and Exjade "false." However, as the Government did not do so, the Court will only focus on the falsity of the certifications made by the pharmacies.

subcontracts) expressly certifying compliance with federal laws (including the AKS) before they could be reimbursed for Myfortic or Exjade claims. The Government does not allege that the pharmacies expressly certified compliance with the AKS each time they submitted a claim; it alleges that, by periodically submitting the paperwork expressly certifying compliance with the AKS, the pharmacies agreed to only accept reimbursement from the federal programs when they complied with federal law.

Second, the Government contends that, by submitting the claims, the pharmacies impliedly certified compliance with all federal laws that are preconditions to payment (including the AKS). To use the Second Circuit's formulation from *Mikes*, the pharmacies submitted claims for reimbursement while "knowing" (as that term is defined in the FCA) "that payment expressly [was] precluded because of" noncompliance with the AKS. 274 F.3d at 700. The Government alleges that the pharmacies impliedly certified compliance with the AKS each time they submitted a claim for Myfortic or Exjade.

But in reality, the Government asserts, the pharmacies were violating the AKS by receiving kickbacks on every single sale of Myfortic and Exjade in exchange for promoting those drugs. So every corresponding claim for Myfortic and Exjade that a pharmacy submitted during the course of the kickback scheme was a "false" claim because, even though the pharmacy had certified that it was not taking kickbacks in exchange for making recommendations, the pharmacy received a kickback for each sale—whether its recommendation yielded the prescription for that particular drug or not.

If the Government's theory of falsity predicated on AKS violations is legally viable, then the Complaint sufficiently pleads the submission of particular claims under Rule 9(b). It contains enough detail to reasonably "identify particular false claims for payment that were

submitted to the government," *Karvelas*, 360 F.3d at 232, and it fulfills the other purposes of Rule 9(b) by providing a factual basis (as opposed to mere speculation) to support the Government's assertion that claims were actually submitted to a government program.

To support its assertion that the kickback schemes resulted in the submission of tainted claims to Medicare and Medicaid, the Complaint recites detailed data about the claims submitted by BioScrip, Baylor, Bryant, Kilgore, Transcript, and Twenty-Ten during the course of the kickback scheme. For example, with respect to Transcript, the Complaint states:

> Any Medicare or Medicaid claim submitted by Transcript for Myfortic dispensed in connection with its illegal arrangement with Novartis was false and ineligible for reimbursement because such a claim was tainted by kickbacks. In that regard, Medicare data shows that, between August 1, 2011, and February 28, 2013, Transcript submitted 614 Myfortic claims to Medicare Part B and obtained more than $354,000 in reimbursement based on such false claims.

Compl. at ¶ 109. The Complaint contains similarly detailed allegations regarding the claims submitted by BioScrip, Baylor, Bryant, Kilgore, and Twenty-Ten. *See id.* at ¶¶ 82, 91, 100, 121, 230.

In other words, the Complaint includes the following identifying information regarding the false claims submitted to government programs: the name of the pharmacy billing the drug, the name of the drug billed, the total number of claims submitted, the approximate total reimbursement amount, the government program that reimbursed the claims, and the precise time period during which the claims were submitted.

If the Government's theory of falsity is legally sufficient, these allegations fulfill the purposes of Rule 9(b). First, the Government provides enough details for Novartis to be able to reasonably identify which of the Medicare claims submitted were "false." The Complaint does not contain vague allegations like the following: "All Medicare claims for Novartis drugs tainted

by the kickback scheme are false." Rather, it contains detailed identifying information like the complaint in *Cardiac Devices*. 221 F.R.D. at 336. The Complaint defines several small pools of claims—for six specific pharmacies, the "false" claims are all the claims for either Exjade or Myfortic submitted by these pharmacies during the time that it was receiving kickbacks to promote that drug, and yet certifying that it was in compliance with the AKS. For each pharmacy, the Complaint states the exact time frame, drug, and government program at issue, and it approximates the number of claims submitted and the total reimbursement amount. With this level of detail, it should not be difficult for Novartis to identify which Medicare and Medicaid claims are alleged to be false—it is *every single claim* in each narrowly defined pool. *See U.S. ex rel. Repko v. Guthrie Clinic*, 557 F. Supp. 2d 522, 527 (M.D. Pa. 2008).

Second, the Government has provided a strong factual basis for its assertion that claims tainted by the Novartis kickback scheme were actually submitted to Medicare and Medicaid, given that it used actual claims data as the basis for its detailed allegations. It broke down this data by pharmacy and recited the total number and dollar amount of claims submitted for each drug. Thus, the Court has robust assurances that the Government is not speculating that the kickback scheme led to the submission of corresponding claims; the Government obtained the actual Medicare and Medicaid claims data on the back end and summarized it in the Complaint.

Accordingly, assuming the viability of the Government's legal falsity theory, the Complaint satisfies Rule 9(b). The fact that the Complaint does not list every one of the pharmacies' claims by date, number, and patient—or even provide a list of example claims—would not render this particular Complaint insufficient. The pleading contains enough information to allow Novartis to figure out which claims the Government contends were false,

and it provides enough detail to demonstrate that the Government is not speculating that claims tainted by the scheme were actually submitted.

In this Circuit, the only case of which I am aware that arguably comes out the other way on a similar false certification theory is *United States ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 09 Civ. 710 (NAM/DEP), 2011 WL 167246 (N.D.N.Y. Jan. 19, 2011). In that case, the plaintiff alleged that, from 2004 to 2011, the defendant dialysis clinic had falsely represented that it was in compliance with a Medicare regulation relating to quality of patient care. The *Blundell* plaintiff adopted a theory similar to the Government's theory in this case: compliance with the Medicare regulation was a precondition to government reimbursement of any Medicare claim submitted by the clinic;[7] therefore, all the Medicare claims the clinic submitted during the period of noncompliance were "false." The complaint gave detailed examples of the clinic's alleged violations relating to patient safety. With respect to the claims, however, the complaint merely alleged "[u]pon information and belief" that the clinic "submitted thousands of claims for reimbursement of Medicare claims." *Id.* at *11. It asserted:

> Any claim that [the clinic] submitted for Medicare reimbursement during the period of time that it was not in compliance with the [Medicare] regulations (at the very least the time that relator was working there, from August 2007 through October 2008) was a false claim because [the clinic] falsely represented that it was in compliance with regulatory criteria.

Id.

The *Blundell* court held that these allegations were insufficient under Rule 9(b). In response to the plaintiff's argument that the complaint gave the defendant clinic adequate notice

[7] The *Blundell* court separately addressed the defendant's alternative argument that the plaintiff failed to state a claim under the FCA. The defendant argued that the plaintiff's theory of legal "falsity" was flawed because the particular Medicare regulation with which the defendant allegedly "impliedly certified" compliance was not a precondition to reimbursement of claims. The court agreed. *See* 2011 WL 167246, at *20.

of the false claims at issue, the court stated that the allegations were "exactly the type of vague and generalized allegation[s] that [are] impermissible under Rule 9(b)." *Id.* at *12. It noted that the plaintiff had "fail[ed] to identify even one, specific fraudulent claim" and "failed to provide details regarding any fraudulent claims including when the purportedly false claims were presented, which employee of defendant submitted the claim or the amount of said claim." *Id.* at *11. Accordingly, the court dismissed the plaintiff's subsection (a)(1)(A) and (a)(1)(B) claims for failure to comply with Rule 9(b).

I think I disagree with my esteemed friend Judge Mordue that the complaint in *Blundell* failed to give the defendant clinic enough information to enable it to figure out which of the claims it submitted (if any) were "false." Under the plaintiff's theory of legal falsity (which is similar to the Government's theory here), the fraudulent scheme rendered *all* the Medicare claims the clinic submitted during the period of noncompliance false—the complaint referred to every single claim the defendant submitted to Medicare from 2004 to 2011.

But in any case, *Blundell* is distinguishable. Even though the complaint in that case gave the defendant sufficient notice of which claims were at issue, it contained only "vague and generalized" (*i.e.*, conclusory) allegations about whether claims were actually submitted to government programs. *Id.* at *12. The complaint did not allege any specifics about the alleged false claims—it merely alleged "upon information and belief" that "thousands of claims" were submitted. Allegations made on "information and belief" are inherently speculative. Further, the utter lack of detail about the claims rendered the *Blundell* plaintiff's allegations equivalent to an assertion that claims "must have been submitted" pursuant to the scheme. Such conjecture is forbidden by Rule 9(b). *See Clausen*, 290 F.3d at 1311. In contrast, the Government's allegations in this case are based on actual Medicare and Medicaid claims data (as opposed to

mere "information and belief"), and the Complaint provides extensive details about the claims submitted to federal programs.

If the Government's legal falsity theory is valid, the Complaint satisfies Rule 9(b). *Blundell* does not convince me otherwise.

But of course, Novartis takes issue with the legal sufficiency of the Government's theory. Novartis contends that, where an underlying AKS violation is involved, the only claims that can be rendered "false" by the scheme are those that were submitted because the kickback scheme worked—*i.e.*, because the recommendation made by a pharmacy (in exchange for kickbacks) succeeded in producing a sale that would not have otherwise been made.

Novartis appears to take this position because of an amendment to the AKS that was passed in March 2010. *See* 42 U.S.C. § 1320a-7b(g). Prior to this amendment, the AKS did not explicitly state that compliance with the statute was a precondition for Medicare or Medicaid reimbursement, and that claims submitted in violation of the AKS were "false" under the FCA—although a number of courts had so held, at least for certain types of claims. *See McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005); *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008); *U.S. v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006); *U.S. ex rel. Pogue v. American Healthcorp., Inc.*, 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996); *but see U.S. ex rel. Kennedy v. Aventis Pharm., Inc.*, 610 F. Supp. 2d 938, 946 (N.D. Ill. 2009).

But in 2010, Congress removed any doubt that may have lingered on that score. *See Hericks v. Lincare Inc.*, No. 07 Civ. 387, 2014 WL 1225660, at *4 (E.D. Pa. Mar. 25, 2014). As

part of the Patient Protection and Affordable Care Act ("PPACA"), it amended the AKS to read: "a claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g) (emphasis added).

Novartis seizes on the phrase "resulting from" to argue a version of "but for" causation—only claims directly caused by (and hence, "resulting from") an illegal recommendation are inconsistent with the certification of AKS compliance, and so are "false."

If Novartis is correct, then the Complaint is deficient (as to the claims submitted after enactment of the AKS amendment)[8] for not identifying with particularity the "false" Myfortic and Exjade claims that were submitted because of a pharmacy's recommendation. Because only a subset of the Medicare/Medicaid claims described in the Complaint would qualify as false, Novartis would need more information to be able to identify the false claims at issue. The Government could then satisfy Rule 9(b) by either providing examples of false claims (like the plaintiff in *Wells Fargo*), or by providing sufficient identifying information about the particular false claims (like the plaintiff in *Cardiac Devices*). *See* 2013 WL 5312564, at *17; 221 F.R.D. at 337.

In short, Rule 9(b) sufficiency depends on whether the Government's theory passes muster as a matter of law. Unfortunately, this particular Rule 9(b) motion is not attached to a more general Rule 12(b)(6) motion, and the parties have not fully briefed the issue. I can see the merit in the Government's theory and I have problems with Novartis's theory—especially in a case where, as is alleged here, the payment of a kickback was not conditioned on a particular claim's resulting from the success of the scheme. But I need more briefing.

[8] The March 2010 amendment to the Anti-Kickback Statute is not retroactive and, thus, does not apply to any claims for payment submitted before its enactment. *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52 n.4 (D. Mass. 2011).

If Novartis's "but for" causation requirement were the law, the Myfortic claims submitted by Bryant would not be "false" unless at least *a* reason, and perhaps *the* reason, that a particular patient was prescribed Myfortic was *because* Bryant recommended the drug to his doctor and not because of legitimate medical reasons; it would be irrelevant that Bryant nonetheless received a kickback for that sale. Similarly, Exjade claims submitted by BioScrip would not be false unless the patient ordered a refill *because* BioScrip convinced him to do so; it would not matter that BioScrip received a kickback on every single sale of Exjade. Such a rule would significantly restrict the definition of legally "false" claims in the kickback context.

In sum, I confess error. I thought (as Novartis apparently thought when it moved to dismiss under Rule 9(b) alone) that it would be easier and more productive to decide the Rule 9(b) motion first. In fact, I cannot decide the Rule 9(b) motion until I decide the Rule 12(b)(6) motions challenging the legal sufficiency of the Government's (and the Relator's) Complaint. Two such motions are presently pending against the Relator's Complaint in this case. Novartis needs to make its motion promptly, and to brief it fully, so that this issue can be resolved.

Novartis has until June 13, 2014 to move to dismiss the Government's and/or the Relator's Complaints pursuant to Rule 12(b)(6). The Plaintiffs have until June 27, 2014 to submit responsive papers. Novartis's reply will be due on July 3, 2014. This schedule may not be altered *for any reason* (except to accelerate it); no extensions can or will be granted.

Novartis's motion to dismiss the subsection (a)(1)(A) claims (Counts 1 and 5) and the subsection (a)(1)(B) claims (Counts 2 and 6) is denied without prejudice.

III. Subsection (a)(1)(C) Claims

Novartis also moves to dismiss the Government's two subsection (a)(1)(C) claims (Counts 3 and 7) pursuant to Rule 9(b).

Subsection (a)(1)(C) provides for liability where the defendant "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)"—meaning conspires to commit a substantive FCA violation. 31 U.S.C. § 3729(a)(1)(C). To prove a claim under this subsection, a plaintiff must show: (1) an unlawful agreement by the defendant to violate the FCA, and (2) at least one overt act performed in furtherance of that agreement. *See Grubbs*, 565 F.3d at 193; *U.S. ex rel. Sterling v. Health Ins. Plan of Greater New York, Inc.*, No. 06 Civ. 1141 (PAC), 2008 WL 4449448, at *4 (S.D.N.Y. Sept. 30, 2008). Because conspiracy is an inchoate crime, the plaintiff need not prove that the defendant actually achieved the object of the conspiracy and completed a substantive FCA violation (such as the presentment of a false claim).

Since no false claim need have been submitted for subsection (a)(1)(C) liability to attach, no claim need be identified with particularity. Novartis does not otherwise challenge the particularity of the Government's allegations regarding the subsection (a)(1)(C) claims. Accordingly, the motion to dismiss for failure to plead fraud with particularity is denied as to Counts 3 and 7.

IV. State Law Claims

Finally, Novartis moves to dismiss the Government's state law claims. The Government brings two claims for unjust enrichment (Counts 4 and 8) and one claim for payment by mistake of fact (Count 9). Novartis moves to dismiss these claims pursuant to Rule 9(b).

The heightened pleading standard of Rule 9(b) applies to state common law claims where those claims are premised on a defendant's underlying fraudulent conduct, including the submission of fraudulent claims to government programs. *See O'Brien v. National Property Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991); *Silverman Partners, L.P. v. First Bank*, 687 F. Supp. 2d 269, 288 (E.D.N.Y. 2010).

The only argument that Novartis makes in support of its motion to dismiss these claims is that the Government "fails to articulate how [Novartis] was unlawfully enriched." Def. Br. at 19.

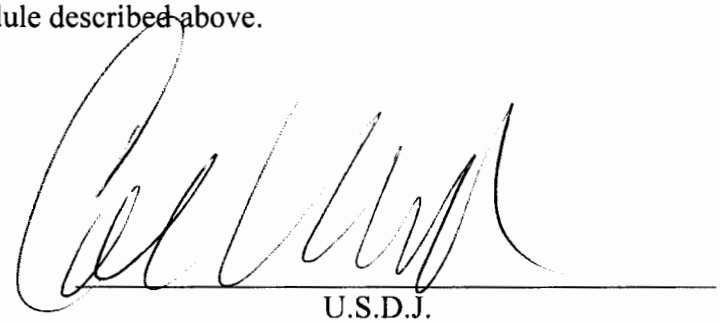
Novartis is plainly wrong. The entire Complaint is premised on allegations that the Government reimbursed pharmacies for false claims for Novartis prescription drugs. It also asserts that Novartis, in the normal course, received money from the pharmacies for these drugs. Further, the Government alleges that Novartis's sales of Exjade and Myfortic increased during the course of the kickback scheme. Thus, the Complaint sufficiently articulates how Novartis was unlawfully enriched.

As Novartis makes no other arguments to support its motion to dismiss these state law claims for failure to plead with particularity, the motion is denied as to Counts 4, 8, and 9.

CONCLUSION

For the foregoing reasons, Novartis's motion to dismiss pursuant to Rule 9(b) is denied. The Clerk of the Court is directed to close out the motion at Docket No. 137 and to remove same from the Court's list of pending motions. Novartis must submit any motion to dismiss pursuant to Rule 12(b)(6) according to the schedule described above.

Dated: May 29, 2014



U.S.D.J.

BY ECF TO ALL COUNSEL